



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,659	02/20/2007	Peter Schwind	BPD-102US	5376
31344	7590	12/07/2009	EXAMINER	
RATNERPRESTIA			NGUYEN, BAO THUY L	
P.O. BOX 1596			ART UNIT	
WILMINGTON, DE 19899			PAPER NUMBER	
			1641	
			MAIL DATE	
			DELIVERY MODE	
			12/07/2009	
			PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



Art Unit: 1641

### **DETAILED ACTION**

1. The amendment dated 18 August 2009 has been received.
2. Claim 25-26 have been added.
3. Claim 1, 3-9 and 20-26 are pending.
4. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3-9, 22, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisberg (US 6,103,536) in view of Eisinger et al (US 4,943,522).

Geisberg teaches a device comprising a single membrane having an application zone, at least one group of indicator zones having reagents appropriate to bind the analytes and at least one absorption region. See column 4, lines 13--38. Geisberg teaches multiple indicator zones for detecting a plurality of analytes and further teaches that for each analyte, a separate series of particular zones and detection zones can be placed in parallel on one comparatively wide strip. See column 8, lines 12-26.

With respect to claim 3, Geisberg teaches that the indicator zones may be arranged in a linear row.

Art Unit: 1641

With respect to claim 4, Geisberg teaches antibodies and other ligands. See column 12, lines 42-55.

With respect to claim 6, Geisberg teaches solid support comprising nitrocellulose or fiberglass, etc. See column 8, lines 34-55.

With respect to claims 7 and 9, Geisberg teaches that the solid support can partially or fully enclosed in a moisture-impermeable, inert casing that can be transparent, translucent or opaque. See column 10, lines 54-67.

With respect to claim 8, Geisberg teaches a backing to increase handling strength. See column 10, lines 28-42.

With respect to claim 22, Geisberg teaches a circular confirmation where the sample receiving zone would be placed at the center of the circle and the indicator zones are arranged in concentric rings radiating from the center. See column 8, lines 26-33.

Geisberg differs from the instant invention in failing to teach antibodies to blood group antigens.

Eisinger, however, teaches device and method for detecting blood group antigens using antibodies. See columns 14-18. Eisinger also teaches using positive controls in the assay and specifically teaches rabbit anti-erythrocyte antibodies for use as a control reagent. See column 22, lines 11-13.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the antibodies taught by Eisinger in the device of Geisberg for detecting blood group antigens because such reagent is well known in the art and Geisberg teaches that their device maybe modify to detect a variety of analytes using appropriate reagents.

Art Unit: 1641

It also would have been obvious to one of ordinary skill in the art at the time the invention was made to include a control zone using the reagents taught by Eisinger in the modified device of Geisberg because such a control zone is well known in the art. Specifically, the second signal zone taught by Geisberg can be modified to include anti-erythrocyte antibodies for use as a control zone because doing so would have provide the advantage of a having an internal indicator which will give a signal as to whether the assay procedure has been completed.

6. Claims 20, 21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisberg in view of Eisinger and Gordon et al (US 6,100,099).

See the discussion of Geisberg and Eisinger above. This reference differs from the instant claims in failing to teach indicator zones that are arrange diagonal to each other.

Gordon, however, teaches a device comprising a strip of porous material capable of transporting fluids by capillary action, said strip having at least first and second unique capture reagents immobilized thereon in first and second discrete spots spaced apart from an end used to contact transport fluid, said unique first and second capture reagents being specific for different first and second analytes. Where the second sport is spaced from the first spot in both vertical and horizontal dimensions, vertical being the direction of fluid flow. Gordon also teaches that the device may contain three or more spots, each spaced from one another in both vertical and horizontal dimensions to form a substantially linear, diagonal array of spots. See column 4, lines 26-41. Gordon teaches that this arrangement of indicator zones provides the advantage of having a vertical separation to better differentiate signal from adjacent spots and since having horizontal direction would require a much wider strip in order to achieve the resolution necessary to read the strip, having the diagonal arrangement works best.

Art Unit: 1641

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the indicator zones taught by Geisberg to detect blood group antigens as taught by Eisinger and to arrange them in a diagonal arrangement as taught by Gordon for the advantage of having a vertical separation to better differential signal from adjacent spots and to avoid downstream spots from being shadowed.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1 and 3-9 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-3, 7, 11-12 and 14-15 of copending Application No. 10/563,681. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application

Art Unit: 1641

since the referenced copending application and the instant application are claiming common subject matter, as follows:

Both sets of claims are directed to a device comprising a membrane, an application zone, at least one group of at least two indicator zones, at least one absorption region and the flow directions from the application zone through the indicator zones are substantially parallel and at least two different flow tracks are present.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Response to Arguments***

9. Applicant's arguments filed 18 August 2009 have been fully considered but they are not persuasive.

The arguments with respect to the 112, first paragraph rejection have been fully considered and are deemed persuasive. Paragraph [0023] describes sealing elements that function as a liquid barrier and permit the directional distribution of the sample liquid in the membrane. This liquid barrier is not shown nor described for the indicator zones in figures 3-6. Therefore, the rejection of claims 1, 3-9 and 20-23 for failing to comply with the written description requirement is withdrawn.

The amendments of claim1 necessitate the withdrawal of the 102 rejection; however, claims 1, 3-9, 22 and 26 are rejected under 35 USC 103 as being obvious over Geisberg in view of Eisinger.

Art Unit: 1641

The argument that Geisberg does not teach a device where the indicator zones are arranged in parallel and where the analyte of interest does not pass sequentially through multiple indicator zones is not persuasive.

Geisberg does teach that more than one indicator zones for the *same* analyte is arranged in a series on the test strip, and that sample must pass through the first zone before passing through the second zone, signals from these zones are used in a ratio; however, this is not the embodiment of Geisberg that is relied upon in the rejection. Geisberg specifically teaches an embodiment for the detection of *more than one analyte* (i.e. a plurality of blood group antigens), where for each analyte, a separate series of particulate zones and signal ratio areas can be placed in parallel on one comparatively wide strip. See column 8, lines 24-26. Therefore, Geisberg does teach a device where at least one group of at least two indicator zones (i.e. separate series placed in parallel), each indicator zone comprising a bonding element that is able to bind to the analyte to be tested for as recited in claim 1. The recitation of claim 1 does not make clear that each group of the at least two indicator zones binds to the same analyte. Because the preamble states that the device is for the determination of *a plurality of blood group antigens*, it has been interpreted that each of the at least two indicator zones is adapted to bind to a different blood group antigen since the claim does not define it otherwise. Furthermore, if claim 1 is not to be interpreted this way, it would lack correlation with the preamble since it is not clearly recited that *a plurality of blood groups antigens* are detected.

The argument that Eisinger does not supply the missing elements is not persuasive. Eisinger is cited for its teaching of blood group antigens and their detections. All other elements of claim 1 is taught by Geisberg as stated above.



Art Unit: 1641

The argument with respect to the rejection of Geisberg in view of Gordon has been fully considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

**10.** Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641  
December 4, 2009